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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/680,587  | 10/07/2003  | John Faul            | STFD-01002US0                | 5254             |
| 28554   | 7590        | 04/03/2006           |                              |                  |
| VIERRA MAGEN MARCUS & DENIRO LLP<br>575 MARKET STREET SUITE 2500<br>SAN FRANCISCO, CA 94105 |             |                      | EXAMINER<br>KRAMER, NICOLE R |                  |
|   |             |                      | ART UNIT                     | PAPER NUMBER     |
|   |             |                      | 3762                         |                  |
| DATE MAILED: 04/03/2006   |             |                      |                              |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/680,587

Applicant(s)

FAUL, JOHN

Examiner

Nicole R. Kramer

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-30 is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-13 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 6-10 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/23/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 13 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,067,495 ("Brehm").

Brehm discloses a method of treatment of pain by applying transcutaneous electrical nerve stimulation with a first electrode located approximately at the top of an individual's spine (electrode 33 of Fig. 4) and with a second electrode located approximately at the bottom of the individual's spine (electrode 34 of Fig. 4). Since Brehm discloses placement of the electrodes at the particular claimed locations on the patient's spine, such TENS stimulation necessarily stimulates the sympathetic celiac ganglia and thus inherently results in appetite suppression. The recitation that the claim is directed to a "method of suppressing appetite in an individual" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

With respect to claim 18, Brehm discloses embodiments in which four electrodes are placed on the patient's back (see Figure 6). A first electrode (i.e., electrode 32 or 38) is located to the left of the thoracic spine and a second electrode (i.e., electrode 33 or 34) is located to the right of the thoracic spine.

With respect to claim 19, Brehm discloses embodiments in which four electrodes are placed on the patient's back (see Figure 6). A first electrode (i.e., electrode 32) is located to the left of a first portion of the thoracic spine and a second electrode (i.e., electrode 34) is located to the right of a second portion of the thoracic spine below the first portion.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by "Study on the effect of transcutaneous electric nerve stimulation on obesity" Tian et al., Beijing Da Xue Xue Bao, 2003 June 18; 35 (3) 277-9 (Abstract provided in English).

Tian et al. discloses that a trial conducted between November 2001 - June 2002 revealed that TENS is effective in treating obesity. Tian et al. discloses the steps of applying an electrical current to the skin of the individual in at least one session to stimulate the nerve pathways innervating the stomach (volunteers received TENS at eight acupoints), monitoring the effect of the applied current applied on the individual's appetite (results indicated a gradual decrease of body weight during the trial), and adjusting a stimulation parameter (intensity of the TENS varied depending on the

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individual's sensitivity to electrical stimulation to maintain a comfortable level). The current applied in Richards et al. has a frequency at 2 Hz and a pulse width of 0.6 ms.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Stimulation of auricular acupuncture points in weight loss" (Richards et al., Aust. Fam. Physician, 1998 July, 27 Suppl 2:S73-77) in view of U.S. Patent No. 5,514,175 ("Kim et al").

Richards et al. teaches a method of suppressing appetite in an individual, comprising the steps of applying an electrical current to the skin of the individual in at least one session to stimulate the nerve pathways innervating the stomach (an auricular stimulator for application of transcutaneous electrical nerve stimulation is attached to the acupuncture ear points shenmen and stomach. Examiner considers such stimulation points "to stimulate nerve pathways innervating the stomach" because such stimulation is disclosed as stimulating the auricular branch of the vagal nerve), and monitoring the effect of the applied current applied on the individual's appetite. The current applied in Richards et al. necessarily has a current intensity, pulse frequency and pulse duration. Richards et al. fails to disclose adjusting a stimulation parameter if

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the monitoring step indicates that the application of electrical current step does not suppress the individual's appetite. Kim et al. teaches an auricular electrical stimulator for introducing electrical signals along neurological pathways associated with auricular points for treatment of obesity and inability to maintain a controlled diet (see, for example, col. 2, lines 7-17 and col. 8, lines 6-11). Kim et al. teaches that the physician typically adjusts treatment duration and parameters according to the particular patient and particular malady (see, for example, col. 6, lines 20-40). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method disclosed in Richards et al. such that the treatment parameters are adjusted after the monitoring step as taught by Kim et al. in order to optimize appetite suppression according to the particular patient's condition and preferences.

With respect to claims 2-4, Kim et al. teaches that the physician typically adjusts treatment duration and parameters according to the particular patient and particular malady (see, for example, col. 6, lines 20-40). When such adjustments occur (i.e., after a single session or after a particular number of sessions) would be an obvious matter of design choice for the practicing physician in order to optimize appetite suppression according to the particular patient's condition and preferences.

With respect to claim 5, Kim et al. discloses that each session of treatment may last approximately one-half hour (see col. 5, line 19).

With respect to claim 11, Kim et al. discloses that applying an electrical current to the skin of the individual comprises the steps of applying a current having a current intensity of between 10 to 145 microamps (see col. 6, lines 36-40).

With respect to claim 12, Kim et al. discloses that the frequency of the signals may be adjusted as desired (see col. 6, lines 34-36).

***Allowable Subject Matter***

6. Claims 20-35 are allowed.
7. Claims 6-10 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. The following is a statement of reasons for the indication of allowable subject matter:

Examiner considers U.S. Patent Application Publication 2003/0181959 ("Dobak, III") to be the closest prior art of record. Dobak, III teaches a method for treatment of gastrointestinal disorders by electrical stimulation of various areas of the sympathetic nervous system, such as the celiac ganglia (see paragraph 0017). Dobak, III teaches that such stimulation may be used for treating obesity, as well as anorexia, bulimia, gastroparesis, irritable bowel syndrome, and other gastrointestinal disorders (see paragraph 0022). However, Dobak, III teaches stimulation of the celiac ganglia via implanted electrodes and thus fails to teach transcutaneous electric nerve stimulation (TENS) applied to the skin of a patient at particular claimed locations on the patient's spine. Further, it would not have been obvious to modify the method of Dobak, III to utilize TENS because Dobak, III involves selective electrical activation of particular sympathetic neurons of a nerve.

In addition, a prior art search revealed several documents relating to transcutaneous electric nerve stimulation (TENS) for various gastrointestinal disorders, such as obesity or gastroparesis (such prior art includes the following articles: (1) "Stimulation of auricular acupuncture points in weight loss," Richards et al., Aust. Fam. Physician, 1998 July, 27 Suppl 2:S73-77; (2) "Study on the effect of transcutaneous electric nerve stimulation on obesity" Tian et al., Beijing Da Xue Xue Bao, 2003 June 18; 35 (3) 277-9 (Abstract provided in English); and (3) "The Effect of Transcutaneous Nerve Stimulation (TENS) on Gastric Electrical Activity," Furgala et al., Journal of Physiology and Pharmacology 2001, 52, 4, 603-610.). These articles teach the application of TENS for gastrointestinal disorders, but fail to teach stimulation of the celiac ganglia via particular claimed locations on the patient's spine (Richards et al. teaches stimulation of auricular points, Tian et al. teaches stimulation of acupoints, and Furgala et al. teaches stimulation via electrodes located on the non-dominant hand). Further, it would not have been obvious to modify the method of using TENS disclosed in the above articles to stimulate the celiac ganglia via particular claimed locations on the patient's spine because the articles involve stimulation of acupoints rather than stimulation of particular nerves.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:



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U.S. Patent No. 6,775,573 ("Schuler et al.") teaches a method and device for controlling sympathetic nerve stimulation of the gastrointestinal tract. One form of a device (10) is shown in Fig 1 and includes at least one treatment member 12 such as an electrode and a control module 14 (see col. 4, lines 28-50). Waveform signals known to control gastrointestinal functioning are sent into sympathetic nerve targets (see col. 4, lines 45-50).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK

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3/22/06

  
George Manuel  
Primary Examiner